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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,682	08/18/2008	**Yukimitsu Suda**	TOS-170-USA-PCT	2820

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EXAMINER	
JONES JR., ROBERT STOCKTON	
ART UNIT	**PAPER NUMBER**
1762	
MAIL DATE	**DELIVERY MODE**
08/17/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,682	SUDA ET AL.	
	Examiner	Art Unit	
	ROBERT JONES JR.	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

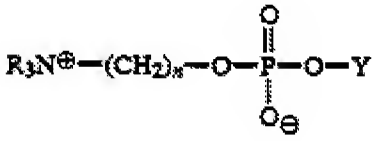
DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

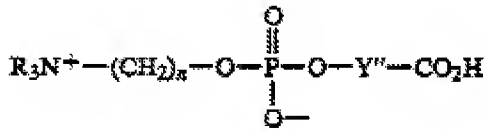
2. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers in view of Matsuda.

3. Bowers teaches a process for treating synthetic polymers to improve their ocular, hemo, and biocompatibility. Said polymers are widely employed in hard, soft, and intraocular lenses (col. 1, lines 6-12). Bowers' process comprises the steps of (a) where appropriate, activating the surface to be treated; and (b) treating the surface with a compound of general formula (I) (col. 1, lines 29-40):



Step (a) may be omitted where the polymer surface has sufficient free hydroxyl groups for reaction with compounds of formula (I) (col. 4, lines 43-46).

4. Suitable compounds according to formula (I) include carboxylic acid derivatives of phosphorylcholine (col. 9, lines 19-30):



(V)

5. Y" is a group such as -$(CH_2)_p$-, wherein p is preferably 1-6 (col. 9, lines 28-30; col. 1, lines 52-53). Thus, Bowers discloses a process which results in a contact lens material having hydroxyl groups which have been functionalized by a compound identical to the claimed formula (2) wherein n=1-6.

6. Bowers' treatment process is preferably conducted in aqueous medium using a sodium bicarbonate buffer (col. 5, lines 33-38). Therefore, Bowers does not teach that the claimed method is carried out in an organic solvent.

7. In the same field of endeavor, Matsuda teaches the formation of contact lenses (Abstract). Matsuda's method involves formation of an ester bond. The ester bonding reaction can be effected by allowing a carboxylic acid derivative to react with a hydroxyl group either in an organic solvent such as DMF, DMSO, HMPA, or THF; or in an aqueous solvent or buffer solution (col. 4, lines 33-51). Thus, Matsuda discloses that when forming contact lens materials, esterification reactions are equally successful when carried out in aqueous or organic solvents.

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bowers in view of Matsuda to substitute an organic solvent for an aqueous solution, as these conditions are taught by Matsuda as being equivalents suitable for carrying out esterification reactions with contact lens materials.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers in view of Matsuda as applied to claim 1 above, and further in view of Valint, Jr.

10. Regarding Claim 2, Bowers in view of Matsuda remains as applied to Claim 1 above. Bowers teaches that for synthetic polymers which do not have adequate free surface hydroxyl groups, it is necessary to activate the surface before treatment with the compounds of formula (I) (col. 4, lines 55-60). Bowers does not teach a specific method for achieving hydroxylation of a polymer surface.

11. In the same field of endeavor, Valint teaches a method for the surface treatment of silicone hydrogel contact lenses. In one embodiment, the surface of a lens is coated by subjecting said surface to: a plasma oxidation reaction, followed by a plasma polymerization reaction in the presence of a diolefin. Finally, the resulting carbon layer is rendered hydrophilic by a further plasma oxidation reaction (Abstract). In addition to rendering the surface hydrophilic, Valint's process results in a coating which is resistant to delamination and/or cracking (col. 3, lines 66-67).

12. It would have been obvious to modify Bowers in view of Matsuda as applied above, and further in view of Valint to introduce hydroxyl groups as per Bowers' step (a) through plasma treatment as taught by Valiant. This method is demonstrated as being successful in treatment of contact lens materials, and results in resistance to delamination and cracking.

Response to Arguments

13. The amendment to Claims 1 and 2 is sufficient to overcome the previously presented rejection under 35 USC 112, second paragraph.

14. Applicant's arguments filed 3 June 2011 regarding the rejection of Claims 1 and 2 under 35 USC 103(a) have been fully considered but they are not persuasive.

15. The Applicant argues that Bowers describes a phosphorylcholine carboxyl derivative that has been turned into an active ester, but because no synthetic method is taught, the composition is not reproducible.

16. First, it is noted that the claims do not require a synthetic method for a compound according to formula 2. Only the structure of the compound is recited. Second, it is believed that developing a synthetic strategy to arrive at Bowers' compound is well within the ability of one with an ordinary level of skill in the art of organic synthesis.

17. The Applicant argues that Bowers does not teach that the method is carried out in an organic solvent.

18. This deficiency in Bowers is acknowledged in the rejection under 35 USC 103(a). Additionally, in response to applicant's arguments against Bowers individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

19. The Applicant argues that Matsuda relates to contact lenses in which ester bonding occurs in either organic or aqueous solvent, but does not deal with esterification of a phosphorylcholine group-containing compound according to formula 2.

20. It is true that Matsuda does not disclose esterification of a phosphorylcholine group-containing compound. This aspect of the invention is disclosed by Bowers as set forth in the rejection above. Matsuda is relied upon to demonstrate that after-treatment of hydroxyl-functional contact lens materials by esterification with carboxylic acid derivatives is equally successful in aqueous and organic solvents, and that the two conditions may be used interchangeably. While Matsuda does not teach esterification of compounds identical to Bowers, the basic chemical reaction is the same. One of ordinary skill in the art would reasonably expect esterification reactions between hydroxyl groups and carboxylic acid derivatives to proceed in a similar manner based on the teachings of Matsuda.

21. The Applicant argues that the Examiner has failed to consider evidence of unexpected results presented in the specification. The Applicant states that the experimental results presented in Examples 1 and 2 and Comparative Examples 1-7 indicate that the contact lenses of the present invention unexpectedly suppress protein adsorption.

22. First, it is noted that the Applicant's protein adsorption results presented in Figure 1 are not adequately annotated in such a way as to allow one of ordinary skill in the art to determine their significance. There is no indication of what is being measured on the y-axis, nor are any units or any other form of measurement indicated. It is not immediately clear how or on what scale the Applicant's results measure protein adsorption.

23. Second, suppression of protein adsorption on a contact lens material by treatment with a phosphorylcholine derivative according to formula 2 is not unexpected based on Bowers. Bowers discloses that such treatment results in reduced protein and cell deposition at polymer surfaces (col. 1, lines 26-28). In Example 5, Bowers demonstrates a 96% reduction in protein deposition compared to an untreated lens.

24. Thus, it is evident that the Applicant's experimental results are not sufficient to establish non-obviousness of the claimed subject matter.

25. The Applicant argues that Valint does not disclose an after-treatment of a contact lens material with the claimed phosphorylcholine group-containing compound.

26. In response to applicant's arguments against Valint individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

27. The Applicant argues that there is no suggestion in Valint that the plasma oxidation reaction would be suitable for the after-treatment called for in Claim 2.

28. The type of treatment called for in Claim 2 as it applies to Valint involves the plasma treatment of an eye lens material to introduce hydroxyl groups. Valint is wholly drawn to a process which concludes with plasma oxidation of a soft contact lens material to introduce hydroxyl groups. Thus, Valint is suitable for the type of treatment discussed in Claim 2.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSJ

/DAVID W WU/
Supervisory Patent Examiner, Art Unit 1762